

REMARKS

Status of Claims

Claims 1, 24 and 31 are currently amended.

Claims 2, 30 and 38 were previously canceled.

Claims 1, 3-29 and 31-37 are pending.

Claim Amendments

Applicants have amended independent claims 1 and 24 to expressly recite that the left and right vagus nerves are stimulated by way of implanted electrodes. The electrical signal is applied to both left and right vagi (*i.e.*, left and right branches of the vagus nerve, or bilateral stimulation of the vagus nerve.) This limitation is supported by original claim 31 ("...electrode means for implantation on said right and left branches..."), the Figure; page 11, lines 1-2; page 16, line 4, and elsewhere in the specification.

Claim 31 is currently amended to emphasize that the stimulation is applied in a supradiaphragmatic position which is in the area of the patient's abdomen. This limitation is implicitly supported in Applicants' Figure, which shows exemplary implanted electrode placement on the left and right vagus nerves above the area of the diaphragm connected by leads to a stimulus generator, all in area of patient's abdomen. This limitation is also implicit in the specification at page 12, lines 3-7; page 7, lines 6-7; and page 8, lines 7-9, for example.

Amendments to the Specification

In the specification, in the "Brief Description of the Drawings," the description of the Figure is currently amended to set forth in words the electrode implantation placement that is shown in the drawing. This amendment is consistent with the specification at page 12, lines 3-7; page 7, lines 6-7; page 8, lines 7-9; and page 11, lines 1-2, for example. The areas of the human body that are illustrated in the Figure in simplified form would have been readily identifiable by one of ordinary skill in the art.

The specification is further amended, on page 10, to correct a typographical error which causes "obesity" to be misspelled as "obseity."

Double Patenting

Claims 1, 3-29 and 31-37 are rejected in the Office Action for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of *U.S. Patent No. 6,587,719*. Applicants will submit an appropriate Terminal Disclaimer to obviate this nonstatutory obviousness-type double

patenting rejection. It is respectfully requested that the requirement for the Terminal Disclaimer be held in abeyance until the claims are otherwise considered to be allowable.

Claims 1, 3-29 and 31-37 are also rejected in the Office Action for nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of *U.S. Patent No. 6,609,025* in view of *Kim et al.* (U.S. Patent No. 5,514,175). Regarding the claims that require supradiaphragmatic positioning, it is said that *Kim et al.* show that such a position can be effective in treating obesity since the applicable nerves can be accessed about the head region. Motivation to combine the '025 patent and *Kim et al.* is said to be the same as that which is asserted with respect to the rejection under 35 U.S.C. § 103(a). In reply, Applicants respectfully submit that, at the time of the present invention, the skilled person would have understood that, in the instant specification, the term "the diaphragm" is in the area of the abdomen. The skilled person would have also understood that a "supradiaphragmatic" location, as that term is used in the instant specification and claims, refers to a location within the body that is above the diaphragm and does not include the patient's ears. Notably, the portion the human body illustrated in Applicants' Figure does not include the ears of the patient. Since the diaphragm is an internal body structure, it is implicit that references to electrode placement relative to the diaphragm are intended to refer to a location within the body that is above the diaphragm. Furthermore, there is insufficient motivation to combine the references as proposed in the Office Action for at least the same reasons as discussed below with respect to the § 103(a) rejection. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3-29 and 31-37 are rejected in the Office Action of October 16, 2006 as being unpatentable over *Kim et al.* (U.S. Pat. No. 5,514,175) in view of *Zabara* (U.S. Pat. No. 5,540,734). The Office Action maintains that although *Kim et al.* do not directly stimulate the right and left vagus nerves, a person of ordinary skill in the art given the disclosure of *Kim et al.* would have seen the obviousness of directly applying the stimulus to the nerves to effect obesity control because it is of general knowledge in the art that nerves may effectively be stimulated either indirectly through the skin with an external stimulator unit, or directly through the use of an implanted electrode and/or stimulator.

In response, Applicants respectfully traverse this rejection. Firstly, *Kim et al.* does not teach or suggest the use of implanted electrodes at all and, to the contrary, teaches that external stimulation of a neural pathway from the ears is effective for treating obesity (col. 8, lines 7-10). As discussed above with respect to the claim amendments, claims 1 and 24 are currently amended to require

application of the stimulus by way of implanted electrodes. Applicants respectfully submit that the exclusive focus in *Kim et al.* upon wholly external devices teaches away from devices having implanted electrodes, as claimed in the present invention.

In the Office Action it is said in response to Applicants' prior argument that any modification of *Kim et al.* to provide for direct stimulation of the vagus nerve, as opposed to indirect stimulation, would not have changed the principle of operation, and that providing for direct stimulation of the patient's 10th cranial nerve (vagus) via an implanted system rather than indirect stimulation does not render the *Kim et al.* reference unsatisfactory for its intended purpose of combating obesity.

Applicants respectfully disagree. The MPEP § 2143.01 VI. is quite specific that the proposed modification cannot change the principle of operation of a reference, stating as follows:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.). [emphasis added]

In the instant matter, the modification proposed in the Office Action, *i.e.*, to convert the system of *Kim et al.* to an implantable version, would, similar to the situation in *In re Ratti*, require a substantial reconstruction and redesign of the elements shown in *Kim et al.*, as well as a change in the basic principle under which the *Kim et al.* system was designed to operate. Notably, such a redesign would also take away the intended ability of *Kim et al.*'s device to be used as a totally external, removable headset for treating obesity, with all its attendant advantages.

The Office Action's response that "[p]roviding for direct stimulation of the patient's tenth cranial nerve (vagus) via an implanted system rather than indirect stimulation does not render the *Kim et al.* reference unsatisfactory for its intended purpose of combating obesity" mistakenly disregards the requirement that no substantial reconstruction and redesign of the elements is permitted in a rejection based upon combining references. It is also impermissible to change the

basic principle under which the *Kim et al.* system was designed to operate in making the combination. Since changing the fundamental principle of the *Kim et al.* system from a completely external system to an implanted system would involve precisely such reconstruction and redesign, the proposed combination is improper. Accordingly, sufficient motivation to convert the system of *Kim et al.* into an implantable system has not been established in the Office Action, notwithstanding the possible desirability, in some cases, of an out-of-sight implantable system to avoid the social stigma of wearing a visible contraption while out in public, or the possibility that an implantable system might be desired if a patient's mental facilities are such that he cannot be relied on to attach the treatment device when necessary.

As motivation to combine the teachings of *Zabara* with those of *Kim et al.*, the Office Action asserts that one would reasonably expect an implanted system for vagus nerve stimulation to work equally as well in treating medical, psychiatric or neurological disorders such as obesity, as an external system that indirectly stimulates the vagus nerve by stimulating the ears, given the teaching by *Zabara* that the vagus nerve can be stimulated by either an internal or an external device to treat these conditions, in conjunction with *Kim et al.*'s disclosure that such a neural pathway is applicable to the invention. Applicants again disagree. Persons of skill in the art would have appreciated that external stimulation of the ears, as employed by *Kim et al.*, via multiple auricular points, involves substantially and fundamentally different neural pathways (col. 1, line 65 – col. 2, line 11) than would a stimulus electrode directly implanted on the left and the right vagus nerves. This difference is apparent in the teaching of *Kim et al.* that the device had little efficacy in some cases, and/or had unacceptable side effects. In particular, *Kim et al.* notes that positive results were obtained for only one obesity patient ("Patient F") over the course of 3 weeks, and that Patients G, H and I "could not adjust to the use of the device," when administered for conditions other than obesity (*Kim et al.* col. 8 lines 11-12.) From the teachings of *Kim et al.*, it would not have been reasonably concluded by one of skill in the art that an implanted system for vagus nerve stimulation would work equally as well in treating medical, psychiatric and neurological disorders such as obesity. Therefore, the artisan would not have reasonably concluded that *Kim et al.* teaches stimulation of the same neural pathway as that which is stimulated by the method of any of claims 1, 24 and 31.

It should also be noted that nowhere does *Kim et al.* teach or suggest internal stimulation. The entire purpose of that reference appears to be to provide convenient external stimulation. *Kim et al.* repeatedly states that the goal is to provide a "portable" and "unobtrusive" apparatus to provide stimulation (col. 2 lines 42-43, 45, 63), and the only embodiment provided is external. (See col. 3

lines 9-13, 50, 63-66). With respect to the "external commence signal" in Applicants' claim 6, the Office Action specifically draws attention to the external ON button 10 of *Kim et al.*, and yet fails to appreciate that this teaching of *Kim et al.* limits *Kim et al.* to external systems only.

The Office Action's statement that "it is of general knowledge in the art that implantable systems may be necessary when precise stimulation of the nerve is required so as to avoid unintended stimulation" mistakenly disregards the fact that the entirety of the *Kim et al.* reference suggests that the type of precise stimulation possible only in an implantable device is not necessary, and that use of the external device of *Kim et al.* is advantageous for the treatment of obesity. Therefore, the teachings of *Kim et al.* as a whole teach away from the proposed modification.

With respect to claims 12, 18, 25-29 and 31-35, which require a supradiaphragmatic electrode implantation site, Applicants respectfully submit that, at the time of the present invention, the skilled person would have understood that a "supradiaphragmatic" location, as that term is used in the instant specification and claims, refers to a location within the body that is above the diaphragm in the area of the patient's abdomen, and does not refer to the patient's ears. See the illustration in Applicants' Figure, as evidence. With respect to claims 31, the method of *Kim et al.* does not include stimulation of the left and right vagus nerve anywhere near the abdominal area, in contrast to the express requirement in currently amended claim 31, and in claims 32-35 which depend from claim 31.

For at least the foregoing reasons, claims 1, 24 and 31, and claims 3-23, 25-29 and 32-37 which depend variously therefrom, are nonobvious over the teachings of *Kim et al.* and *Zabara*.

Conclusion

Entry of the amendments and reconsideration of the application and withdrawal of the objections and rejections are requested. Applicants respectfully request allowance of all pending claims. This is believed to be a full and complete response to the Office Action dated October 16, 2006. If any issue in the Office Action has been overlooked or is deemed to be incompletely addressed, Applicants respectfully request the opportunity to supplement this response. It is believed that no extensions of time or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event that any additional extension of time is necessary to allow consideration of this paper, such extension is hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required (including fees for net addition of claims) are hereby authorized to be charged to Deposit Account Number 03-2769 of Conley Rose, P.C., Houston, Texas.

Date

01/12/2007

Respectfully submitted,

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